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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin Purpura

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,885	Applicant(s) PURPURA ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-21 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21 and 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/24/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and IDS filed on 01/24/08 is acknowledged.

Claims 1-8, 11, 13, 14, 17-21 and 23-24 have been amended.

Claims 30-33 have been added. Claims 12 and 22 have been cancelled.

Claims **1-11, 13-21 and 23-33** are under prosecution.

The rejections made under 35 USC 112.1 and 35 USC 112.2 have been withdrawn in view of Applicants amendments of claims.

The following are new rejections.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11, 13-21 and 23-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "and/or" which makes the claim indefinite, the term effective amount without the recitation of effective amount is indefinite because the

metes and bounds of the claim is not defined. The word "subject is indefinite because it is not clear whether the word encompasses only human being or animals too. For claim 14, there is no antecedent basis for protein thus making the claim indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-11, 14-21 and 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP61078351 in view of Kiliaan et al. (WO 01/84961 A2).

JP patent teaches the microcapsules that are composed of lecithin as a component included and gelatin as a coating film, enabling the lecithin and /or other medicines and foods to be easily and simultaneously taken, as the lecithin is prevented from being oxidized and deteriorated (abstract). Lecithin or a mixture of lecithin with food oil, liposoluble vitamins, eicosapentaenoic acid and docosahexanoic acid is used as components. The microcapsule size is disclosed to be preferably 10-2000 micrometer (abstract).

The reference does not specifically teach making functional food to be in various forms as claimed, however, Kiliaan et al. discloses a preparation suitable for the prevention and/or treatment of vascular disorders, comprising the following fractions:

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fraction a) long chain polyunsaturated fatty acids; fraction b) phospholipids, the fraction contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, fraction c) compounds which are a factor in methionine metabolism, which fraction contains at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (abstract). The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5). Triglyceride is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive degeneration and improper functioning associated with kidneys, liver, stomach etc. Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

Based on the teachings of Kiliaan et al., it would have been obvious to one of ordinary skilled in the art to prepare a functional food in any form such as liquid, bar or cookie etc. as claimed. One skilled in the art would have been motivated to prepare the functional food comprising phospholipids such as lecithin in an encapsulated form because the microcapsules are prevented from being oxidized or deteriorated. One skilled in the art would have optimized the various amounts of the components by doing experimental manipulations in order to arrive at the effective amount of the functional

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food. Regarding the particle sizes claimed, it would have been obvious to one of ordinary skill in the art to optimize such parameters by doing experimental manipulations since the Japanese patent teaches the preference of microcapsules to be within 10-200 micrometer. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955). Regarding claim 24, in the absence of specific effective amount, any amount that is provided in the prior art reads on the effective amount. Prior art of Kiliaan teaches normalizing cholesterol levels. Regarding the specific phospholipids claimed in claim 32, it is the position of the examiner that since the prior art teaches inclusion of various phospholipids, inclusion of the specific phospholipids would have been obvious to the formulation taught by the combination of references in the absence of unexpected results.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 61078351 in view of Kiliaan et al. (WO 01/84961 A2) and further in view of Geiss et al. (Geiss (US PG pub.2004/0120985 A1)).

The references do not teach claimed carbohydrates. Geiss et al. discloses functional food for the cognitive functional capacity comprising carbohydrate, proteins, phosphatidylserine, vitamins and fat. The functional food products disclosed are in the form of milk, diet foods, dairy products etc. (see claims). It would have been obvious to

use carbohydrates taught by Geiss et al. in the combination of references taught above because carbohydrates comprising functional food helps in increasing cognitive capacity.

Response to Arguments

7. Applicant's arguments with respect to claims 1-11, 13-21 and 23-33 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 01/24/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

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272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612